

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

GENOMIND, INC.  
2200 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19406

Plaintiff,

v.

UNITEDHEALTH GROUP INC.  
9900 Bren Rd E  
Minnetonka, MN, 55343-4402,

UNITED HEALTHCARE SERVICES, INC.  
9900 Bren Rd E, Ste 300W  
Minnetonka, MN, 55343-4402,

UNITED HEALTHCARE INSURANCE  
COMPANY  
185 Asylum St  
Hartford, CT, 06103-3408,

UNITED HEALTHCARE SERVICE LLC  
9900 Bren Rd E  
Minnetonka, MN 55343,

UNITED BEHAVIORAL HEALTH  
425 Market St FL 18  
San Francisco, CA, 94105-2532,

UMR, INC.  
115 W Wausau Ave  
Wausau, WI 54401,

OXFORD HEALTH PLANS, LLC  
48 Monroe Tpke  
Trumbull, CT, 06611-1341,

OPTUM, INC.  
11000 Optum Cir  
Eden Prairie, MN, 55344-2503

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiff Genomind, Inc. (“Genomind”), based upon personal knowledge as to itself and its own acts, and information and belief as to all other matters formed after an inquiry reasonable under the circumstances, asserts the following in support of its claims against Defendants UnitedHealth Group Inc. and certain of its subsidiaries (collectively, “United,” “UHC,” or “Defendant”):

### **INTRODUCTION**

1. Plaintiff Genomind is a high-quality and well-recognized genetic laboratory that regularly provides medically necessary genetic testing to patients who are beneficiaries under health insurance plans issued or administered by United (“United Insureds”). Many are governed by the Employee Retirement Income Security Act (“ERISA”), 29 U.S.C. § 1001, *et seq.* (“United ERISA Insureds”).

2. Defendant UnitedHealth Group Inc., through its wholly-owned and controlled subsidiaries, including Defendants United HealthCare Services, Inc., United HealthCare Insurance Company, United HealthCare Service LLC, United Behavioral Health, UMR, Inc.,<sup>1</sup> Oxford Health Plans, LLC, and Optum, Inc. (collectively “United,” “UHC,” or “Defendant”), is a fully integrated company that is in the business of insuring and administering commercial health insurance plans (“United Plans”). Many of those plans are governed by ERISA.

3. United administers all United Plans. In that role, United decides what the written terms of the United Plans mean. One way it does so is by interpreting common written plan terms through medical policies, adjudicating claims pursuant to those policies, and then paying resulting claims.

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<sup>1</sup> In bringing this action against United, Genomind explicitly is not bringing direct claims against UMR, Inc. (“UMR”), a UnitedHealthcare subsidiary. Genomind’s only claims against UMR, as part of United, is with respect to the ERISA claims relating to the United ERISA Insureds identified herein.

4. As detailed herein, United engaged in a persistent course of conduct in which it misled Genomind concerning coverage that would be, and was, available for services provided by Genomind to patients insured by United Plans.

5. Reasonably relying on United's misrepresentations and other misconduct, Genomind developed an entirely new version of its genetic test and provided genetic testing services with the expectation of being paid by United, only to have United withhold such payment without reasonable basis and then mislead about why claims were not being paid. Through this action, Genomind seeks appropriate legal and equitable remedies.

6. Genomind is further suing United under ERISA, pursuant to patient-executed assignments of benefits, to remedy United's wrongful denial of Genomind's claims.

### **THE PARTIES**

#### **Plaintiff**

7. Plaintiff Genomind was founded in 2009 with the vision of bringing personalized medicine to neuropsychiatry. Its business provides a proprietary, saliva-based genetic test that predicts patient response to psychiatric medications. The results allow behavioral health providers to prescribe medications that are properly tailored for their patients' genetic makeup, and are therefore more likely to be efficacious and/or well-tolerated. Genomind is a Pennsylvania corporation, with its executive headquarters and testing facility located in King of Prussia, Pennsylvania.

#### **Defendant**

8. Defendant UnitedHealth Group Inc. is a Minnesota corporation with its principal place of business in Minnetonka, Minnesota. It is a fully integrated company that is in the business of insuring and administering commercial health insurance plans. Defendant UnitedHealth Group Inc. operates as, and owns the trademark to, "UnitedHealthcare."

9. Defendants United HealthCare Services, Inc., United HealthCare Insurance Company, United HealthCare Service LLC, United Behavioral Health, UMR, Inc., Oxford Health Plans, LLC, and Optum, Inc. are wholly-owned and controlled subsidiaries of Defendant UnitedHealth Group Inc. UnitedHealthcare's subsidiaries do not operate independently and in their own interests, but serve solely to fulfill the purpose, goals, and policies of UnitedHealth Group Inc.

### **JURISDICTION AND VENUE**

10. Genomind asserts subject matter jurisdiction under 28 U.S.C. § 1331 (federal question jurisdiction), 29 U.S.C. § 1132(e) (ERISA), and 28 U.S.C. § 1367 (supplemental jurisdiction, for the state-law claims asserted herein).

11. Venue is appropriate under 28 U.S.C. § 1391(b)(2) because Plaintiff Genomind is headquartered in this District, and Defendant United's misconduct was directed to Genomind in this District. Venue is also appropriate under 28 U.S.C. § 1391(b)(1) and (c)(2) because Genomind's claims arise from United transacting business in this District, with Genomind and certain United Insureds.

### **FACTUAL ALLEGATIONS**

#### **Behavioral Health Background**

12. The burden of mental health treatment in this country is massive and growing. According to the National Institute of Mental Health, from 2009 to 2013, mental health expenditures in this country group grew from \$147 billion to more than \$201 billion, as efforts were made to treat the nearly 45 million Americans experiencing mental illness (representing one in six people). It is estimated that depression will represent the number one global health burden by 2030, highlighting the need to provide effective and efficient treatment.

13. The problem that faces the behavioral health community, as well as the health insurance industry, is that treatment is empirical and resource intensive. Finding safe and effective treatment for mental health patients can take months of trial and error, with many patients not responding to the first prescribed medication, and many going through multiple failures lasting 8-12 weeks per trial. At the same time, the side effects can become intolerable, while the patients suffer a diminished quality of life and may become so disillusioned that non-compliance becomes a significant problem.

14. It is generally understood, that genetic variations among patients can render various psychiatric medications ineffective or increase the risk of serious side effects. Being able to identify those variations, therefore, maximizes the possibility that the most appropriate medication will be selected for each patient early in the treatment process. This both reduces adverse consequences if the wrong medication is selected and reduces reliance on the blind trial and error method. Genomind's services address that problem.

#### **Genomind's Services**

15. Genomind provides pharmacogenetics testing through its proprietary product, the Genomind® Professional PGx Express™. Prior to August 5, 2019, Genomind's product was known as the Genecept Assay®.<sup>2</sup> A variation of this product, Genomind® Professional PGx Express™ Core Anxiety and Depression, was created in direct response to discussions with United, as described herein.

16. Genomind tests are performed on the patient's saliva, which is obtained either through a spit sample or from a cheek swab. The saliva samples are taken in the office of the

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<sup>2</sup> The terms the Genomind® Professional PGx Express™ and the Genecept Assay® are used interchangeably in this document.

patient's treating health care provider or by the patient at home, after which the sample is sent to Genomind's testing facility in King of Prussia, Pennsylvania.

17. Genomind runs its tests in its state-of-the-art lab, which is accredited by the College of American Pathologists (CAP), certified by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA), and licensed by the New York and Pennsylvania Departments of Health. In its facilities, Genomind is approved and authorized to conduct all tests for which it has submitted benefit claims to United, including the Genecept Assay®.

18. The Genecept Assay® helps increase the likelihood of treatment response by identifying patient-specific genetic markers that indicate which treatments will likely (i) work as intended to address the patient's mental health condition, (ii) not be effective in treating that condition, or (iii) cause adverse reactions or side effects. Genomind's tests, for example, can help detect those at risk for up to 50% increased side effects with particular antidepressants. Once a patient's unique propensities are identified, an appropriate medication can be prescribed, for which the likelihood of a successful treatment is maximized. Importantly, the Food and Drug Administration (FDA) has approved specific labeling that recommends dose adjustments, or contains precautions, warnings or drug-drug interaction statements using certain genetic biomarkers for dozens of different psychiatric medications that are commonly prescribed, as well as hundreds of other drugs, many of which are incorporated into Genomind's gene-drug interaction guide, G-DIG®, which accompanies its genetic assay.

19. Genomind does not decide which patients to test. Rather, it only tests patients for whom the treating behavioral health provider has prescribed its services based on the determination by that provider that Genomind's test is medically necessary and appropriate so as to assist with

identifying the most appropriate psychiatric medications. Genomind has no financial connection with the treating providers, and offers no financial incentives to them.

20. To date, over 15,000 clinicians have ordered Genomind's tests for more than 265,000 patients, with approximately 70% of the clinicians reordering them. Genomind's tests have substantially benefitted those patients, as the tests have allowed treating behavioral health providers to better identify the proper medications to treat the patients' underlying conditions.

**United's Role in Administering Behavioral Health Plans and Its Recent History of Improperly Denying Behavioral Health Coverage**

21. United is the largest administrator of behavioral health claims in the country, operating through UnitedHealth Group's subsidiary United Behavioral Health ("UBH") and serving more than 43 million people.

22. For "fully insured" Plans—which are offered, underwritten, and administered by United—United makes benefit payments for covered treatments from its own assets in exchange for premiums paid by the employer and/or employees. For "self-insured" Plans—under which United receives an administrative fee in exchange for administering the plan—United makes the benefit payment and then is reimbursed from the Plan itself, which is funded by the self-insuring Plan sponsor.

23. In a recent decision from the United States District Court for the Northern District of California, where UBH is headquartered, UBH was found to have engaged in "pervasive and long-standing violations of ERISA," by "den[ying] mental health and substance use disorder treatment coverage to tens of thousands of class members using internal guidelines that were inconsistent with the terms of the class members' health insurance plans." *Wit v. United Behavioral Health*, 2020 WL 6479273, \*1 (N.D. Cal. Nov. 3, 2020) (describing ERISA trial verdict reached in *Wit v. United Behavioral Health*, 2019 WL 1033730 (N.D. Cal. Mar. 5, 2019)). Moreover, the

court found that UBH's conduct was intentional, as it "engaged in this course of conduct deliberately, to protect its bottom line," and, "[t]o conceal its misconduct," had "lied to state regulators," with "UBH executives with responsibility for drafting and implementing the guidelines [having] deliberately attempted to mislead the Court at trial in this matter." *Id.*

24. As a result of UBH's egregious misconduct, the court in *Wit* not only found UBH to be liable under ERISA, but it issued a ground-breaking remedies order. Among other things, the court has ordered UBH to adopt and apply the proper coverage guidelines which are consistent with generally accepted standards of care; to reprocess more than 67,000 behavioral health claims that it had improperly denied based on its reliance on its flawed and overly restrictive internal guidelines; to provide training to all UBH employees engaged in making coverage determinations, whether during the mandatory reprocessing or going forward with new claims; and to provide training to all UBH employees, including senior executives, concerning ERISA and what it means to be an ERISA fiduciary. Significantly, all of these steps will be implemented under the oversight of a Special Master that the court will appoint to ensure that UBH is following the court's orders.

25. In adopting these remedies, the court highlighted the fact that UBH, operating as the behavioral health arm of UnitedHealth Group, simply could not be trusted to fulfill its obligations, and that there was a "significant danger of recurrent violation." *Id.* at \*42.

#### **United's Purported Recognition of the Medical Necessity of Genomind's Services**

26. As the use of genetic and molecular lab testing became more common with regard to numerous health care conditions, United announced in August 2017 that, as of November 1, 2017, it would require prior authorization relating to such services for certain of its plans. For those plans, United required that such services had to be approved in advance. The process was overseen by Beacon Laboratory Benefit Solutions, Inc. ("Beacon"), a lab services management company



that operated as United's agent in registering participating labs for the program and managing the online notification/prior authorization request system.

27. At this time, United did not interpret the United Plans to cover genetic testing for mental health issues, such as the Genecept Assay®. According to United, such testing was experimental and investigational as defined by a written exclusion found in each of those plans. The only exception to this categorical bar to coverage was United's drug metabolism policy, pursuant to which United deemed testing of three particular genes to not be experimental. During this period, Genomind tested for these three genes and was reimbursed by United.

28. From August through November 2017, Genomind engaged with Beacon, as United's agent, to register for and ensure that Genomind was able to comply with United's new prior authorization protocol.

29. After United's prior authorization process for genetic testing was initiated on November 1, 2017, Genomind extensively engaged with United for two years additional years in an effort to ensure that it, and the providers who prescribe its tests, were able to comply with United's prior authorization requirements.

30. On August 1, 2019, United announced that, as of October 1, 2019, it would cover genetic testing for mental health issues such as that provided by Genomind. In a new Commercial Medical Policy, United stated that the use of pharmacogenetic Multi-Gene Panels to guide therapy decisions was "proven and medically necessary for antidepressants and antipsychotics medication" when all of three criteria are met:

- The individual has a diagnosis of major depressive disorder or anxiety;
- The individual has failed at least one prior medication to treat their condition; and
- The Multi-Gene Panel has no more than 15 relevant genes.

31. In issuing this new policy, United explicitly confirmed that Genomind's proprietary product, the Genecept Assay®, was one of the products that was removed from United's list of unproven and not medically necessary panels. This demonstrated that United now recognized that the Genecept Assay® was a proven and medically necessary genetic test that was a covered service under the United Plans when the three conditions identified above were satisfied.

32. As soon as Genomind learned of the policy change, it contacted United to begin working to ensure that its product would be covered under the policy. In an August 9, 2019 email, Genomind employee Ariy Krishnaraj wrote to Dr. Jennifer Malin, Senior Medical Director of Oncology and Genetics of United Healthcare:

We were extremely pleased to read the recent UHC Commercial Medical Policy on Pharmacogenetic Testing that endorses the use of pharmacogenetic multi-gene panel to guide therapy decisions as proven and medically necessary for antidepressants and antipsychotics when the patient has a diagnosis of major depressive disorder or anxiety and provided it meets the other criteria laid out in the policy. We were also pleased that our product, Genecept Assay, was one of the products that was removed from the list of unproven and not medically necessary panels.

In the process of getting us ready for the policy effective date of Oct 1, we have a few clarifying questions regarding the medical policy specifically regarding the criteria mentioned in the policy. We want to ensure we have a clear understanding of the policy so that we can educate our customers accordingly helping smooth implementation of the policy among customers.

Towards that end, we would like to request a time on your calendar, preferably over the next couple of weeks, for a conference call with you.

33. Over the next several months Genomind engaged in extensive communications with senior United representatives to ensure that Genomind would be able to have its Genecept Assay® claims properly submitted to United, consistent with the United coverage policy, so that Genomind would receive proper benefit payments for such services.

34. As part of these communications, United told Genomind that because United's coverage policy required that any Multi-Gene Panel have no more than 15 relevant genes,

Genomind's traditional 24-gene panel would not be deemed a covered service by United, even if the 15 covered genes were included within the 24-gene panel. United further told Genomind that if Genomind developed a new test that only tested the 15 covered genes, the 15-gene test would be covered.

35. As a result, Genomind spent months and invested substantial financial resources working with United to develop the Genomind® Professional PGx Express™ Core Anxiety and Depression test (the "Core 15 Test"), a unique 15-gene panel that it could use for United patients to ensure coverage and payment by United. The months-long effort consumed every department at Genomind and constituted a company-wide shift in focus. Genomind's activities to develop the 15-gene test included but were not limited to reviewing medical literature to assess the most relevant genes (which Genomind in turn shared with United); creating new packaging; developing new information technology, customer service, and billing workflows; training the sales force; establishing a separate marketing plan; and training physicians on the new test. In addition, Genomind hired another company to help ordering clinicians obtain prior authorizations; purchased a segmentation model to guide its sales and marketing efforts for the new product; developed an internal compensation plan for the sales force to foster adoption of the new product; and spent over a year working to obtain a Proprietary Laboratory Analyses (PLA) Code for the new test, at United's direction. In sum, Genomind's time, labor, and other investments to develop, test, and roll out the 15-gene product well exceeded one million dollars.

36. In investing substantial time and financial resources to develop the Core 15 Test, Genomind reasonably relied on United's representations that testing with Genomind's new 15-gene panel would be covered. Several examples of those representations follow.

37. In a telephone call between Genomind and United representatives on August 23, 2019, United confirmed that the Genecept Assay® would now be a covered service, subject to the

three requirements. In particular, United explained that Genomind would be able to get coverage for its genetic tests so long as it developed a panel of 15 genes, rather than the 24-gene panel that Genomind was then using, and that Genomind would be able to submit and be paid directly for those claims.

38. On that same day, Dr. Jennifer Malin, United's Senior Medical Director of Oncology and Genetics, emailed Kathryn Stough, United's National Lab Program Manager, copying Genomind's Chief Medical Officer, Dr. David Krause. In the email, Dr. Malin stated: "This email is to introduce you to Genomind who have a test that our PGx policy will now cover as of 10/1."

39. Dr. Krause responded to this email later that day, expressing an interest in further discussing the revised gene panel that Genomind would develop to ensure consistency with the United policy.

40. Dr. Malin scheduled a follow-up meeting with Genomind in California on October 2, 2019. The primary purpose of the meeting was to allow Genomind to demonstrate to Dr. Malin the Core 15 Test that would satisfy United's coverage policy for the Genecept Assay®. In advance of the October 2 in-person meeting, Genomind had a conference call with Dr. Malin on September 4, 2019, to go over various details relating to Genomind's plans, including how Genomind was going to be developing the Core 15 Test as a subset of its traditional 24-gene panel in order to ensure that Genomind would be able to bill United and be paid for its services, consistent with United's coverage policy.

41. On the September 4, 2019 call, Dr. Malin and others at United confirmed that Genomind's product, when reduced to a 15-gene panel, would be covered by United; that providers who wished to use the Genomind test could obtain approval through the prior authorization process overseen by Beacon, where applicable; and that these services would be covered with Genomind

be proceeding as an out-of-network provider, unless and until Genomind's application to become in-network was processed and accepted.

42. While Genomind was working with Dr. Malin to confirm its ability to create and use the Core 15 Test that would be covered by United, Genomind also communicated with Beacon to ensure that Genomind would be in a position to get prior authorization for its genetic tests through the Beacon portal.

43. Around that same time, Genomind also submitted a completed application to become a United in-network provider. The application included Genomind's CAP certification, CLIA Certificate of Accreditation, and Clinical Laboratory Permits from the New York and Pennsylvania Departments of Health. Genomind's application was forwarded to United's National Ancillary Strategy Provider Inquiry Group, and identified as a "Referral from Dr. Malin."

44. On a September 6, 2019 call between Genomind and United representatives, Ms. Stough and others at United again confirmed that Genomind's Core 15 Test would receive prior authorization and be covered under United's new coverage policy while Genomind continued as an out-of-network provider. At the same time, Ms. Stough encouraged Genomind to continue pursuing an in-network contract, expressing the view that Genomind was ideally situated to be in-network with United. Following the call, she sent a "credentialing application" to Genomind, to further advance its effort to go in-network.

45. On September 10 and 11, 2019, Genomind emailed Ms. Barnes from Beacon and Ms. Stough from United to highlight Genomind's new Core 15 Test that was created to conform to United's coverage policy.

46. During the scheduled in-person meeting on October, 2, 2019 between Dr. Malin, Dr. Krause, and Genomind's CEO Shawn O'Brien, United again reassured Genomind that

everything was set for Genomind to be able to obtain prior authorization, when necessary, and coverage and payment for its Core 15 Test, consistent with United's coverage policy.

**United's Improper Refusal to Cover Genomind's Services**

47. United implemented its coverage policy on October 1, 2019. By that time, United had repeatedly assured Genomind that its services would now be able to receive prior authorization and be covered as an out-of-network service.

48. In reasonable reliance on those representations, Genomind conducted its genetic tests for United insureds whose treating behavioral health care providers had prescribed them, after having submitted such claims for prior authorization and being approved by United. Thereafter, Genomind submitted the claims for payment of the Core 15 Test based on the reasonable expectation that it would be paid. Yet, for the vast majority of such tests, United did not pay the benefits, without any appropriate justification and continued its misconduct.

49. After the new policy went into effect, Genomind continued to have regular contacts with United and/or Beacon, as United's agent, to address difficulties that arose either with treating providers obtaining necessary prior authorization or with claims submitted by Genomind. Throughout the process, United and Beacon continued to reassure Genomind that there were no problems with Genomind submitting or being paid for its claims and that it should continue to provide the tests and submit the claims.

50. For example, in response to certain difficulties that occurred with regard to prior authorization, Ms. Barnes, for Beacon, explained in an email that the prior authorization program "does not apply to [certain] lines of business," and then referred Genomind to a United website that identified the "line of business [which] falls within this program: <https://www.uhcprovider.com/en/prior-auth-advance-notification/genetic-molecular-lab.html>.

51. The current version of that website reports that “[t]he notification/prior authorization requirement for certain genetic and molecular tests applies to: Certain UnitedHealthcare commercial benefit plans when UnitedHealthcare is the primary payer; Oxford Health Insurance; [and] UnitedHealthcare Community Plan in select states,” adding:

Ordering care providers will complete the notification/prior authorization process online or over the phone. Labs must register their tests to participate as part of the Genetic and Molecular Lab Testing Notification/Prior Authorization process.

On its website, United further discloses that “[n]otification/prior authorization for genetic and molecular tests has been required for certain UnitedHealthcare commercial benefit plans since Nov. 1, 2017,” with various plans being added over time, including Oxford as of April 1, 2020. This meant, of course, that Oxford did *not* require prior authorization for the Genomind test prior to that date. Genomind communicated this information to its ordering providers, so they would know which United plans required prior authorization, and which ones did not.

52. On November 1, 2019, Genomind raised another issue with Ms. Stough—that it had received several denials or very little reimbursement because of a “so-called agreement” that Genomind had with Multiplan. A United Explanation of Benefits (EOB) reflected that Genomind had been paid for services provided to a patient insured under an ERISA plan issued by United. In explaining how the claim was processed, United stated that there were “Payer Initiated Reductions” applied based on a “Claim Specific Negotiated Discount,” such that the patient bore no financial responsibility for the treatment. The EOB then stated: “This out-of-network provider has accepted a discount for this service based on an agreement with Multiplan.” The problem with this communication was that Genomind did not have an agreement with Multiplan and, as an out-of-network provider, had never agreed to accept a negotiated discounted rate from United. That was precisely why Genomind was seeking to go in-network, pursuant to which it would accept a

negotiated discounted rate in exchange for being given greater and more efficient access to United insureds.

53. Ms. Stough responded by pointing to United's "LINK online system," which was wholly unrelated to the fact that United was improperly imposing a discounted rate on Genomind.

54. Throughout November and December 2019, as providers prescribed the Core 15 Test based on repeated assurances from United and/or Beacon that Genomind's services would be covered under the United Plans, Genomind continued to engage with United and/or Beacon whenever issues arose over getting prior authorization.

55. Another in-person meeting between Genomind and United representatives was held at United offices in Minnetonka on January 17, 2020. Many representatives from Genomind attended, including its CEO, President, Director of Market Access, and Chief Medical Officer. At the meeting United and Genomind discussed the status of Genomind's ongoing submission of claims relating to the Genecept Assay® being used for United Insureds, as well as Genomind's on-going application to go in-network.

56. In a January 20, 2020 follow-up email to United after the in-person meeting, Genomind summarized that it had been working closely with United to ensure that its claims were being processed and paid properly, and was "fully utilizing" United's prior authorization process "to ensure that the test ordered complies completely with United Healthcare's medical policy" so that Genomind could continue to treat United's insurers and be reasonably compensated in return. The email also reminded United that Genomind had developed a specific test, the Core 15 Test, specifically to comply with United's current policy.

57. Throughout January and February 2020, Genomind continued to engage directly with United and Beacon to ensure that the process was running smoothly so that Genomind could be assured that it would be covered for the Genecept Assay®. Soon, however, Genomind



recognized that its claims were frequently not being paid by United, even when prior authorization had been received.

58. On February 20, 2020, Genomind's Reimbursement Leader Grace Innamorato emailed Ms. Stough to raise concerns over delays in United payments for services that had been pre-authorized, stating:

I have been attempting to make some sense in the pattern of UHC payments to Genomind, Inc. and even within some lines of business the payments are inconsistent. Recently payments have been delayed even with the Prior Authorization in place.

I have attached several for your review. It would greatly be appreciated if you can investigate as to why [these] payments tend to be both erratic and sporadic.

59. On March 2, 2020, a call was held between a number of representatives of United, Beacon, and Genomind to address ongoing issues. After the meeting, Genomind requested that Beacon and United provide specific patient examples from their summary of issues so that Genomind could address them.

60. In the weeks following the call, Genomind repeatedly engaged with United and Beacon to facilitate approvals for numerous patients whose treating providers had prescribed the Genecept Assay®. Although United and Beacon continued to represent that Genomind's services were covered, United was still withholding payments on a number of Genomind claims that had already been pre-authorized. In a May 29, 2020 email, Ms. Innamorato wrote to Ms. Stough that only 12% of Genomind's Core 15 claims to United had been processed for payment upon initial submission, and only 20% after an appeal had been completed—even though prior authorization had been received when necessary.

61. After Ms. Stough responded by email on June 3, 2020 to inquire as to whether Genomind had submitted its claims through the "regular channel," Ms. Innamorato confirmed that Genomind was following the claims process by having the clinicians use the prior authorization

process via the Beacon portal and submitting its claims issues through the proper channels. Ms. Innamorato requested to speak with someone about resolving the matter.

62. Ms. Stough asserted only that “Prior Authorization is not a guarantee of payment,” adding that Genomind could follow a process to seek “reconsideration.” Ms. Stough’s response was not made in good faith: While in general, prior authorization does not guarantee payment, since the service at issue may ultimately change from what was originally anticipated, that does not occur with genetic testing. In order to receive pre-authorization for a Core 15 Test, a patient must have been diagnosed with a qualifying mental health disorder and United’s coverage guidelines must have been satisfied. The test itself does not change. As a result, there is no reasonable basis for United to deny payment after having pre-authorized the service. Moreover, United was frequently not paying the claims, but without issuing a formal denial, leaving Genomind in limbo without to handle the unpaid claim.

63. In an email response on June 4, 2020, Ms. Innamorato wrote: “I think you may agree that when we are following the processes and complying with the coverage policy, being paid only 10% of the time on over 800 claims is not really consistent with a few exceptions of ‘[Prior Authorization] does not guarantee payment.’” Ms. Innamorato again requested assistance with resolving the issue.

64. After further unsuccessful efforts to address United’s failure to pay for the pre-approved Genomind services, Ms. Innamorato emailed Ms. Stough and Shawn D. Schwartz, Director of National Lab at United Healthcare Services, explaining that since October 1, 2019, Genomind had submitted 961 claims for its Genomind Professional PGx Express CORE 15 Test consistent with United’s policy, but that less than 20% of such claims had been paid. She continued that Genomind “believes this is egregious as all the Genomind claims have proven medical necessity and we have followed the policy and process pristinely.” The email attached a summary

of the many hundreds of unpaid claims for “bulk reconsideration,” in the format provided for such reconsideration by United. Finally, the email noted that Genomind was incurring additional costs to ship its tests directly to United plan members to help keep them safe during the COVID-19 pandemic.

65. On June 26, 2020, Ms. Stough responded to Ms. Innamorato, but without justifying United’s persistent failure to pay. Instead, she asserted that there appeared to be “multi-denial reasons,” and that Genomind had 365 days to appeal.

66. In a response later that day, Ms. Innamorato requested a call with United and Beacon.

67. On July 6, 2020, Ms. Stough emailed Ms. Innamorato to explain that the “reconsideration escalation project” to resolve the issue with United’s consistent failure to pay Genomind had been submitted to the appropriate group at United, but added that “these projects are running between 45-60 business days.” Ms. Innamorato emailed Ms. Stough on August 27, 2020, seeking an update of the status of the project, but never received a response.

68. Shortly after Ms. Stough’s July 6, 2020 email, Genomind began receiving form letters from United which did not deny claims, but sought further back-up documentation. In a July 17, 2020 letter, for example, United stated:

We received the above claim for [United insured]. Before we can process this claim, we need more information. Please send all of the treatment records for every date of service on the claim. These records should include but may not be limited to the first date of service referenced above [July 1, 2020]. We frequently request treatment records as part of our routine claims processing to help us determine eligible expenses under the patient’s health benefit plan.

69. The letter then provided a specific request for *all* related medical records for the patient, “including but not limited to, copies of: history and physical; presenting symptoms and complaints; findings on examination; lab test results; x-rays; consultation reports; daily progress

notes; medication records relative to the treatment; durable medical equipment records that include copies of the physician orders that list the referring physician's name, the invoice and the delivery statement showing the date of receive; any other information that's not listed but part of the patient's treatment records." United also required Genomind to "*mail* the treatment records" to United's offices in Atlanta, Georgia, an outdated and inefficient mode of communication apparently designed to foster delay.

70. This was also not made in good faith. United knows full well that Genomind does not have access to these records, nor would they be relevant to its claims. As of October 1, 2019, United adopted a policy that would cover genetic testing, including the Genecept Assay®, so long as the individual had a diagnosis of major depressive disorder or anxiety; the individual had failed at least one prior medication to treat their condition; and the Multi-Gene Panel had no more than 15 relevant genes. Full medical records are not necessary to ensure that these requirements are satisfied. Further, for many of these claims, Genomind had already submitted all necessary documentation and United and/or Beacon had verified that the criteria were satisfied in providing prior authorization.

71. In an effort to address the inappropriate practices reflected in letters such as this, Ms. Innamorato emailed Ms. Stough, attaching a copy of the letter summarized above, and asking if an online portal or fax machine could be used for the requested records rather than having to use the mail during a pandemic, with much of the workforce working from home.

72. In response, Ms. Stough merely forwarded to Ms. Innamorato a form document from United titled "Participating Laboratories Frequently Addressed Questions," which failed to address the issues raised by Genomind.

73. With United failing to respond to Genomind's repeated entreaties for assistance, Genomind had no choice but to send United a demand letter. In the letter dated July 29, 2020, Genomind's outside counsel reiterated United's failure to pay, stating:

Genomind has been reliant on your Pharmacogenetic Testing Policies since October 1<sup>st</sup> 2019, and on your Prior Authorization process, all to the benefit of your customers or patients and UnitedHealthcare. We urge you to take this seriously and respond at your earliest convenience.

74. United's response letter on September 1, 2020 failed to substantively address why United had failed to pay so many claims that had already received prior authorization. In particular, United asserted that from October 2019 through July 2020, there were 1,208 prior authorization requests submitted through Beacon, of which 910 were approved, 13 were duplicates or cancelled, 278 were denied and 7 were pending clinical review. It then asserted generally that the 278 denials were valid. As for the 910 approved claims, of which 701 had *not* been paid, United merely asked that Genomind "clarify" if the codes it had submitted for the unpaid claims "match the codes which the providers submitted and which were approved on the requests for prior authorization."

75. The letter reflected yet a further effort to delay resolution of the dispute, so as to further enable United to avoid payment. After all, United had the information concerning which codes had been submitted for payment, as well as what had been authorized, and therefore did not need to ask Genomind to provide such information. Moreover, since Genomind's services were limited to the genetic testing of the 15-gene panel which had already been pre-authorized there is no reason to believe that Genomind would suddenly change what "codes" it would use to reflect such tests, and, indeed, its actual bills did match those identified during the prior authorization in virtually all circumstances.

76. Through outside counsel, Genomind responded on September 10, 2020. In its response, Genomind had to correct numerous factual misstatements by United. First, it pointed out

that as of June 24, 2020, Genomind had submitted 910 claims for the Core 15 Tests, which Genomind had been forced to create to meet United's policy. Of that amount, 827 successfully received prior authorization, not the full 910 that United asserted in its letter. The remaining 83 claims arose out of plans that did not require prior authorization. Of those that were pre-authorized, only 156 (or 17%) were actually authorized for payment by United, even though they all were pre-approved as satisfying United's coverage requirements. Second, the letter pointed out that an additional 198 Core 15 Tests had been pre-approved by United, up through September 2, 2020, of which only *one* was approved for payment without an appeal, while an additional 16 were approved after Genomind was forced to appeal, for a total payment approval percentage of only 8%. Thus, in total, United had only approved for payment 14.9% of the Core 15 Tests that Beacon or United had already pre-authorized.

77. United responded to the Genomind letter on September 21, 2020. In its new letter, United again merely raised questions without providing any justification for the failure to pay so many Genomind claims that had received prior authorization. As an initial matter, United asked about the claims that did not require prior authorization, even though United should already have been aware of which of its own plans did not fall within the prior authorization policy. Moreover, United continued to delay resolution by seeking information that United already had, including "documentation that the tests performed and CPT codes Genomind submitted with the unpaid claims match the tests and CPT codes which the providers submitted and which were approved on the requests for prior authorization."

78. Because United already had the information on what had been submitted by ordering providers seeking prior authorization for the Genecept Assay®, as well as what was submitted for final payment after the tests were performed, it did not need to require Genomind to gather that information either.

79. United's request for more information also makes little sense. The prior authorizations were for the 15-gene test that had been specifically been developed by Genomind and approved by United, so there was no reason to anticipate a variation in how that test was billed. Genomind billed the same service that United pre-authorized in virtually all circumstances.

80. With respect to the 198 new pre-authorized tests for which it failed to make payment, United offered no rational explanation. Instead, United simply stated:

We need to better understand the universe/timing of claims referenced here. The timing outlined from prior authorization to claim submission and appeal does not seem accurate. Claims submitted in late August or September may still be under review if information is missing or if the test is determined to be unproven. The peer to peer process is available prior to appeal; please clarify if that has been utilized.

81. Once more, United's response makes little sense. To the extent United had pre-authorized Genomind to perform the 15-gene test for a patient who satisfied United's coverage requirements, there is no reason to believe that there would be "missing information" and no basis for United to suggest that the test might be "determined to be unproven," since United had already agreed to the precise test that was being used. Similarly, United failed to explain how a "peer to peer process" would even apply to this situation -- Genomind is merely billing for a test it designed for United in circumstances in which United had pre-authorized the test.

82. Following United's response, a virtual meeting between Genomind and United was scheduled for September 25, 2020. In advance of that meeting, Genomind's CEO wrote United a letter dated September 24, 2020 to address the issues raised in United's September 10 communication. In responding to United's inquiries, Genomind's CEO wrote:

We confirm that 910 is the correct number of claims at issue as of the time of writing of our original letter. That number has since increased to 1202 claims submitted.

Your assertion that all submitted claims required prior authorization (PA) is not correct. For example, Oxford HealthCare's requirements changed from no PA

required to PA required as of April 1, 2020. . . . As both our letters and yours reflect, however, the vast majority of claims were, in fact, submitted for preauthorization through UHC's approved process, and were granted authorization.

83. As for United's suggestion that the final submitted claim may have differed from what had been pre-authorized, the Genomind CEO further disabused United of that notion, stating:

Effective 10/2/2019, the CORE 15/FULL 24 Gene Panels were registered on the Beacon LBS Portal upon approval and the procedure codes being billed match the test exactly. The comment in your letter appears to be applicable to general services that receive pre-authorization, such as surgeries, where the circumstances – and billed CPT Codes – could change when the services are actually provided. As you should understand, that is unlikely to happen with the services provided by Genomind, in which we obtain prior authorization to provide specific genetic testing and then perform those specific tests.

84. As for the suggestion of an appeal process following a peer-to-peer review, the Genomind CEO described why that was inapplicable:

Genomind understands that recent claims may still be under review. At no time, however, was a Peer-to-Peer meeting offered based upon a claim denial. The only opportunity for a Peer-to-Peer is when there is a "pending" Medical Review of a submitted prior authorization, not after a claim has been finalized as non-payment. Given the volume of unpaid claims with valid PAs, Genomind does not believe the Peer-to-Peer process is feasible in any event, given that there seems to be a systematic, if not deliberate, denial of valid claims. Moreover, under the types of services at issue here, involving genetic testing, the Peer-to-Peer process seems unlikely to come into play, contrary to when traditional medical necessity issues arise over other types of medical care that must be adjusted to specific diagnoses and healthcare conditions of the patient.

85. Finally, the Genomind CEO highlighted how Genomind was being damaged by United's recalcitrance. He emphasized that Genomind had spent a substantial amount of time working with United to ensure compliance with United's policies, and yet United had not paid for the vast majority of Core 15 Tests; that United had no reasonable basis for refusing to pay anything for Genomind's 24-gene panel (e.g., up to the 15 covered genes), since United had already acknowledged that those 15 genes are appropriate for testing; and that United had effectively ignored Genomind for the past year, leading to many of millions of dollars in unpaid services.



86. During the virtual meeting between Genomind and United on September 25, 2020, Genomind was shocked to hear that United had no further explanation or justification for the systemic pattern of not paying for the vast majority of the Genomind claims. Rather, United merely offered to “initiate” an investigation, which has not resolved the issues detailed herein.

87. In further contradiction of the representations it repeatedly made to Genomind, United has also directly discouraged its in-network providers from using Genomind’s services due to its status as an out-of-network provider. In letters to various in-network providers, for example, United has cited to its in-network contracts which require compliance with United’s internal protocol that calls for only referring patients to other in-network providers in non-emergent circumstances. Such letters then identify the provider’s referral to Genomind as a violation of this protocol, thereby subjecting the provider to potential penalties, including termination of the in-network contract. The sole purpose of such letters is to discourage in-network providers from using Genomind’s services, despite the fact that Genomind offers the best available genetic testing for patients suffering from behavioral health conditions. Yet, United has repeatedly assured Genomind that it could continue treating United-insureds on an out-of-network basis, and being paid for doing so, a representation that was false and misleading in light of United’s actions.

**United’s Claims of Alleged Overpayments to Genomind**

88. As Genomind was seeking payment from United for covered (and often pre-authorized) services, United engaged in an effort to “recover” funds from Genomind that had properly been paid in the past.

89. By letter dated January 31, 2020, Lucile Rankin, an Investigations Consultant for United’s Special Investigations Unit (“SIU”), wrote to Genomind that United “conducted a recent review of claims submitted by your office and identified an apparent overpayment of

\$5,085,950.02 that was made to you for claims with paid dates between May 5, 2015 and October 31, 2019 for laboratory claims.”

90. Although United did not make a formal demand for repayment in the letter, it threatened to issue one if it did not receive a substantive response from Genomind within 15 days.

91. While United purported to offer Genomind an “opportunity” to respond, such offer was facially disingenuous and in bad faith. United provided virtually no information in the letter concerning the basis for the demand. Among other things, it did not identify the specific charges that were supposedly overpaid, why United deemed them to be overpaid, what policies United had applied in reaching that decision, or what plans were at issue. Instead, United simply asserted, without further explanation:

An analysis was conducted of the claims submitted by Genomind versus the CLIA lab certification codes (specialties/subspecialties) CMS certified for Genomind to perform; (900) Cyogenetics effective May 5, 2015 through January 24, 2017 and (310) Routine Chemistry effective January 25, 2017 to determine the \$5,085,950.02 overpayment.

Genomind had no ability to respond substantively to United’s conclusions, as they were not explained.

92. Thomas Hess, Genomind’s Chief Financial Officer, responded to United’s letter on February 12, 2020. Mr. Hess noted that Genomind had not received sufficient information from United to understand the basis for its conclusion that there had been a \$5 million overpayment, pointing out that “[w]ithout such information, we are placed in a very difficult position as we are unable to determine to what arguments we should be responding.” Mr. Hess then explained in detail what services Genomind provided, including a discussion of the various certifications it has received which authorized it to perform the genetic tests for which it had billed United.

93. Over two months later, on April 21, 2020, Ms. Rankin finally responded to Mr. Hess. Her sole explanation, however, was a list of CPT codes with the assertion that

“UnitedHealthcare paid claims submitted by Genomind utilizing the following CPT codes, which the records received from Genomind did not support the lab was certified by CMS CLIA or CAP to perform [such] tests.”

94. This was also not a good faith position, as explained in a May 13, 2020 letter to United from David J. Robbins, Genomind’s Chief Scientific Officer & Laboratory Directory:

UHC is indicating that the findings are relative to Genomind’s CLIA certification and that the certification does not support Genomind’s right to perform specific tests, CPT Codes, as it applies under CLIA law. We disagree entirely with United’s assessment of this issue. As we previously explained in our prior letter, Genomind is, in fact, CLIA certified, and similarly is a CAP, NYSDOH and PA state certified/licensed laboratory. As a result, Genomind is properly able to conduct and bill for genetic tests.

95. After United failed to respond to the May 13 letter, on July 29, 2020, Genomind’s CEO emailed Ms. Rankin and Robert Lucyk, a member of United’s SIU team, stating that Genomind had not heard back from United and that Genomind considered the matter closed.

96. United did not respond either to Genomind’s May 13 or July 29 letters, such that Genomind reasonably believed that the SIU investigation was no longer active.

**United’s Late and Faulty Justification for Denying Genomind’s Benefit Payments**

97. As described above, Genomind engaged in a series of calls, meetings, and related correspondence with United in an effort to resolve the underlying issues and prevent the need to file this lawsuit. These efforts all failed due to United’s continued misrepresentations, bad faith and otherwise inequitable conduct.

98. Genomind learned for the first time, in October 2020, that United’s actual reason for its material delay in payments for Genomind’s claims was the SIU investigation. Without providing any prior notice to Genomind, in April 2020, United secretly placed Genomind on “prepayment review,” such that its claims were routinely upheld as medical records were reviewed and the purported SIU investigation continued.

99. This was more bad faith. United’s flawed conclusion that Genomind may have been overpaid from 2015 through the end of September 2019 is wholly unrelated to the test Genomind developed for United or the claims that Genomind submitted after October 1, 2019, when United changed its policy to cover the Genecept Assay®. Particularly since United stated that its January 31 letter was “not a demand for payment,” there was no reasonable basis for United to use the issues raised in that letter as a secret basis for it to refuse to pay benefits to Genomind for claims that it submitted thereafter, especially after it had received prior authorization from United or its agent, Beacon.

100. Had United not misled Genomind and otherwise acted inequitably, as alleged herein, Genomind would not have developed the Core 15 Test, continued to engage with United, or continue to provide tests to United insureds.

### **ERISA Claims**

101. The majority of claims submitted by Genomind concerned tests provided to patients insured by health insurance plans governed by ERISA (“United ERISA Plans”).

102. Pursuant to United’s Medical Policy effective October 1, 2019, United interpreted the terms of the United ERISA Plans to deem mental-health-related genetic testing of 15 genes, such as the test provided by Genomind, to be both medically necessary and not experimental, so long as those tests were provided to patients who satisfied the criteria.

103. In denying coverage of the United ERISA Insureds’ genetic testing provided by Genomind, therefore, United violated the written terms of the relevant United ERISA Plans—as described in further detail below.

104. Each United ERISA Insured signed a form which authorized Genomind to test the genetic sample, and further stated that “I authorize Genomind, its agents or contractors to bill my insurance carrier(s) and assign any payments from my insurance carrier to Genomind, its agents

or contractors,” while adding that “I agree that I am financially responsible for any out of pocket costs including insurance deductibles or co-payment required by my insurance carrier.”

105. Based on the “assignment” of benefit payments included in this provision, Genomind has the legal right to assert the ERISA claims brought herein.

106. United repeatedly and consistently accepted the enforceability of those assignments. It engaged directly with Genomind, and not these patients, and treated Genomind as the party to whom benefits were legally owed. It worked directly with Genomind to allow for the submission of these claims; repeatedly assured Genomind that the claims would generally be covered; worked with Genomind to ensure that the claims met the United billing and coverage policies; permitted Genomind to appeal denied claims; paid any benefits that were deemed to be covered to Genomind; repeatedly met with Genomind and its counsel to discuss underlying issues with claims; and pursued purported overpayments made by United to Genomind by working with Genomind and not involving the underlying United insured patients.

107. Genomind provided both the Core 15 Test and the full 24-gene panel to United ERISA insureds.

108. The United ERISA Insureds who have assigned their benefit payments to Genomind include 3391 insureds whose claims for coverage for their Genomind tests have been denied or not covered by United. Of those, United ERISA Insureds 1-1022 had their genetic samples tested using the Core 15 Test (the “Core 15 Insureds”); United ERISA Insureds 1023-3391 were tested using the original full 24-gene test (the “Full 24 Insureds”).

109. To protect the privacy of the 3391 United ERISA Insureds, who have received behavioral health services and have had benefit claims submitted on their behalf, the names and identifies of these insureds are not specified in this public complaint. However, subject to an

appropriate confidentiality agreement, Genomind will disclose to United the identity of the 3391 United ERISA Insureds.

**Genomind's Claims for Core 15 Insureds**

110. Genomind submitted claims for the Core 15 Test for Core 15 Insureds (United ERISA Insureds 1-1022). Genomind billed \$5,400 for each Core 15 Test, such that it has billed a total of \$5,518,800 for these tests. Despite the fact that many of these claims were pre-authorized by United and/or its agent, Beacon, when prior authorization was applicable to the particular line of business in which the plan was issued, and that all of the claims fall squarely within United's coverage policy, United has nevertheless failed to pay *any* of these claims. While United did cover and pay benefits for a small percentage of Core 15 Tests that were billed by Genomind, Genomind is not asserting ERISA causes of action in this complaint relating to those claims.

111. Genomind's standard practice is to file internal appeals to challenge United's wrongful denials of the Core 15 claims. United either denied or ignored those appeals, and refused to meaningfully address the substance of Genomind's appeals. Indeed, United has failed to identify any plan term that supports these denials. United's stated rationales for denying coverage of Genomind's Core 15 Test are baseless, including but not limited to those detailed below.

**United's Improper Denials Based on its "POS 81" Policy**

112. United regularly denied Genomind's claims because Genomind designated the "Place of Service" ("POS") for the testing at issue with number 81 when it submitted a claim.

113. The Centers for Medicare & Medicaid Services ("CMS") is a federal agency within the U.S. Department of Health and Human Services ("HHS") that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Insurance Program ("CHIP"), and health insurance portability standards. As part of its work, CMS issues Place of Service Codes for Professional Claims which, according to CMS, "should be used

on professional claims to specify the entity where service(s) were rendered.” *See* [https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place\\_of\\_Service\\_Code\\_Set](https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set) (updated October 2019) (“CMS POS Codes”).

114. The CMS POS Codes are used universally in the United States for submitting insurance claims relating to professional health care services, including by laboratories like Genomind, to all insurance plans, whether Medicare, Medicaid or private insurance, such as that issued and/or administered by United.

115. Under the CMS POS Codes, Place of Service Code 81 is used to indicate that the Place of Service is an “Independent Laboratory,” which is described as “a laboratory certified to perform diagnostic and/or clinical tests independent of an institution or a physician’s office.”

116. Genomind is an Independent Laboratory under the CMS POS Codes and therefore uses POS 81 to indicate the place of service for its tests. To the best of Genomind’s knowledge, no other charges are submitted by any provider with respect to the Genomind test, including charges for taking the saliva sample that is forwarded to Genomind for testing. This is the appropriate POS designation used by Genomind for its services and is consistent with generally accepted standards for coding and claim submissions. Indeed, if Genomind used a different POS designation it would be violating appropriate coding standards.

117. United has nevertheless taken the position that Genomind should not use POS 81 when submitting a claim, but instead should use the POS code for the location in which the sample is taken, such as POS 11 for “Office.”

118. These designations of other than POS 81, including POS 11 for Office, are inappropriate designations, however, because they do not represent where the service was provided, which is at the Genomind’s testing lab. CMS and all other private health insurers with

which Genomind interacts expect Genomind to use POS 81 for its claims. Only United asserts that POS 81 is an inappropriate POS designation.

119. United's improper internal policy relating to the use of the POS 81 designation has been repeatedly used by United to deny coverage for Genomind claims. For example, United denied coverage for one of Genomind's Core 15 Test, which was performed on May 3, 2020. After Genomind appealed the denial, United upheld the decision, stating that "[t]his service is not reimbursable for this provider in this place of service (req. by FA. Eff. 7/12/10)." United did not explain its citation. Then, in a section entitled "Claim/Coding Logic," United further explained the basis for its denial:

Not supported. Per United Healthcare Laboratory services policy, the place of service reported should be where the specimen was obtained. The submitted medical records contain discrepancies with the reported place of service noted on the submitted claim form. Therefore, the billed code and place of service cannot be supported.

120. United has taken the firm position that this policy is appropriate, and has refused to reconsider any denials based on that policy.

121. In denying coverage for the use of the POS 81 designation, however, United failed to identify the written plan term that purportedly supports the denial. These denials were also wrongful and unreasonable because United knows that Genomind is an independent lab that performs its tests at its own location, after samples are collected by the patients or their treating providers and because Genomind properly used the POS 81 designation.

*United's Improper Denials Based on the Experimental/  
Investigational Exclusion or as Not Medically Necessary*

122. United denied many of Genomind's claims on the ground that the test was experimental/investigational or otherwise was not medically necessary. Not only did United again fail to identify the specific plan language it was relying upon, its own medical policy recognized



that the genetic test provided by Genomind was not experimental and was medically necessary. All of the claims submitted for the Genomind Cor 15 Test satisfied United's coverage policy, such that the subsequent denials issued by denial were improper.

*Lack of Prior Authorization*

123. For a number of claims submitted by Genomind, United denied them on the basis that they lack prior authorization. Yet again, however, United issued the denial without identifying what provision of the applicable health insurance policy require such pre-authorization for the Genomind test, in violation of ERISA.

124. In any event, United's denials lacked any valid basis, since the only claims for the Core 15 Tests which were submitted by Genomind without prior authorization was when the underlying insurance plan was in a line of business for which United did not require prior authorization.

*United's Improper Flagging and Denying of Genomind Claims*

125. United also refused to pay many claims submitted by Genomind without issuing any explanation at all, or based on explanations that concealed the actual reason – United had placed the flag on Genomind due to the undisclosed SIU investigation.

126. In “flagging” Genomind and thereby placing its claims in limbo, United violated ERISA and the term of its plans, which do not authorize such denials.

127. These denials were also wrongful because Genomind has all the necessary licenses, and the flag that SIU imposed was based on licensure concerns that Genomind addressed during the aforementioned discussions with United, and which United recognized as having been resolved.

**Genomind's Claims for "Full 24" Insureds**

128. Genomind has also submitted claims for each of the Full 24 Insureds (United ERISA Insureds 1023-3391), for which it billed \$5,850 for each such test. In total, Genomind has therefore billed United \$13,858,650 for these tests, for which it has received no payments. In each case, United denied coverage on the ground that the services were inconsistent with United's internal coverage policy. This is wrongful and unreasonable. Genomind's full 24-gene panel tests each of the 15 genes that United has conceded should be tested consistent with generally accepted standards. Thus, while it might be reasonable to refuse to pay for the testing of the additional 9 genes, there is no reasonable basis for denying coverage for testing of the 15 genes that is covered.

129. As described with respect to the Core 15 Tests, Genomind's standard practice is to appeal all denials of coverage, including for these claims for the Full 24 Insureds. United, however, has denied those appeals, or has ignored them entirely, such that Genomind has exhausted its administrative remedies.

130. Moreover, as detailed herein, United has adopted a firm policy that it will not provide prior authorization for or cover a claim that Genomind has performed a test on a United insured patient based on the 24-gene panel. Based on this firm policy, United has also confirmed that it will not reconsider or reverse on appeal any denials for coverage of Genomind's 24-gene panel.

131. In denying coverage for the Full 24-gene test, United has also violated ERISA by failing to identify what provision of its underlying health insurance plans permit it to issue such blanket denials, notwithstanding that 15 of the genes to be tested have been recognized as medically necessary and covered under the United plans.

**COUNT I**  
**Breach of Implied-in-Fact Contract**  
(Against Defendant UnitedHealth Group Inc.)

132. Genomind realleges and incorporates by reference as if set forth fully herein the allegations contained in paragraphs 1 through 131.

133. Genomind established a policy, effective October 1, 2019, that it would cover genetic testing with multi-gene panels for mental health disorders, provided that the panel included 15 genes. At the same time, Genomind explicitly confirmed that Genomind's Genecept Assay® was one of the products that was removed from United's list of unproven and not medically necessary panels.

134. Genomind further engaged in lengthy communications with United concerning its creation and use of the Core 15 Test to ensure that this 15-gene panel would satisfy United's coverage criteria. Top United officials repeatedly confirmed that Genomind's 15-gene test would be covered under the new policy as an out-of-network service.

135. Genomind submitted numerous claims to United and/or its agent Beacon for prior authorization, seeking confirmation that it was authorized to test United insureds with the Genecept Assay®. United and/or Beacon repeatedly granted prior authorization for the test.

136. Genomind and United agreed that Genomind's Core 15 Test would be covered as an out-of-network service, as manifested by, among other things, United creating the Core 15 Test for the sole purpose of meeting United's specifications, United officials confirming on multiple occasions that Genomind's 15-gene test would be covered as an out-of-network service, and United providing prior authorization for that test where applicable.

137. Upon receiving confirmation that its tests met United's standards, and prior authorization (where applicable), Genomind obtained genetic samples from the United insureds and tested such samples using the Genecept Assay®. Thereafter, Genomind provided the results

of such tests to the United insureds or their treating providers, which were then used to determine the appropriate medication to treat their underlying mental health conditions.

138. Upon completing these tests, Genomind submitted bills to United, using the billing codes that United and/or its agent Beacon agreed were proper and payable.

139. Genomind provided the services to the United insureds, and submitted the bills, based on the implied-in-fact contract that Genomind and United had entered into, pursuant to which United agreed to pay Genomind for its services in an amount consistent with United's methodology for out-of-network services.

140. In issuing the prior authorization to Genomind, while providing other assurances that Genomind's Core 15 Test satisfied United's coverage policy, United was accepting Genomind's offer to provide such services in exchange for proper reimbursement. This established valid and enforceable contracts between United and Genomind.

141. By performing the Core 15 Test for the United insureds, as pre-authorized by United when applicable, Genomind performed under the implied-in-fact contracts with United.

142. United failed to pay Genomind for these services, in breach of these implied-in-fact contracts.

143. Genomind has repeatedly demanded payment under the terms of these contracts, but United has refused to make payment.

144. Genomind has been injured by the refusal of the Defendant to make the payments required under the contracts.

**COUNT II**  
**Promissory Estoppel**  
(Against Defendant UnitedHealth Group Inc.)

145. Genomind realleges and incorporates by reference as if set forth fully herein the allegations contained in paragraphs 1 through 131.

146. As set forth herein, in establishing a policy that it would cover 15-gene panels for mental health disorders, assuring Genomind that it would cover a 15-gene version of the Genecept Assay® if Genomind developed one, assuring Genomind that the Core 15 Test satisfied United's coverage policy whether or not prior authorization was required for the particular plan at issue, and providing prior authorization to Genomind for testing United insured patients with the Core 15 Test where applicable, United made promises to Genomind to accept bills from Genomind and to reimburse it for the Core 15 Test in an amount consistent with the terms and conditions of the underlying health care plans as applicable to each United insured treated by Genomind.

147. Genomind is not challenging through this Count the amount that United owes to Genomind under the terms of the applicable health insurance plans, but only the fact that United has refused to pay Genomind for the services it had authorized Genomind to perform for the United Insureds. However, Genomind reserves the right to challenge the amount United pays for Genomind's services, to the extent such payments are not consistent with the terms and conditions of its underlying plan documents or otherwise in compliance with applicable laws and regulations.

148. Genomind reasonably, substantially and detrimentally relied on said promises from United and/or its agent Beacon by, among other things, investing substantial time and money in developing the Core 15 Test for the sole purpose of fulfilling United's arbitrary 15-gene criterion, and providing the testing services that it offered to the United Insureds.

149. Genomind's reliance on United's promises was foreseeable to United, as United and Genomind officials exchanged communications about the development of the Core 15 Test and United assured Genomind its test would be covered.

150. Injustice can be avoided only by enforcing Defendant's promises to pay.

**COUNT III**  
**Quantum Meruit**

(Against Defendant UnitedHealth Group Inc.)

151. Genomind realleges and incorporates by reference as if set forth fully herein the allegations contained in paragraphs 1 through 131.

152. Genomind performed valuable services for United by, among other things, providing testing with the Core 15 Test for the benefit of the United Insureds.

153. United enjoyed the benefits of such services by having fulfilled its obligations to the United Insureds and their plan sponsors by providing access to health care providers, in this case Genomind, for medically necessary services, in exchange for receiving premiums or administrative services from the United Insureds or their employers.

154. United accepted and retained the foregoing benefits.

155. United was reasonably notified that Genomind expected to be paid for services it provided to the United Insureds. Among other things, before providing such services, Genomind obtained prior authorization from United and/or its agent Beacon with respect to the plans for which prior authorization applied and, further, engaged in lengthy communications with United and/or Beacon in which Genomind received assurances that the Core 15 Test satisfied United's coverage policies.

156. Under these circumstances, Genomind is entitled to receive the reasonable value of the services it provided.

**COUNT IV**  
**Unjust Enrichment**

(Against Defendant UnitedHealth Group Inc.)

157. Genomind realleges and incorporates by reference as if set forth fully herein the allegations contained in paragraphs 1 through 131

158. United obtained benefits from Genomind through the taking of undue advantage.

159. As set forth herein, without limitation, United and/or its agent Beacon consistently represented that: the United Insureds had health benefits coverage with or through United for the services at issue; and United would pay Genomind for such services. In connection with these claims, United and/or Beacon also specifically provided prior authorization for the services provided by Genomind with respect to those plans for which prior authorization applied, thereby verifying that Genomind would be permitted to bill United for such services and would be paid for providing such services to the United Insureds. United and/or Beacon, as United's agent, further repeatedly assured Genomind that its Core 15 Test fell within United's internal coverage policy.

160. United enjoyed and retained the benefits of such services by having fulfilled its obligations to the United Insureds and their plan sponsors by providing access to health care providers, in this case Genomind, for medically necessary services, in exchange for receiving premiums or administrative services from the United Insureds or their employers.

161. Due to United's improper refusal to pay Genomind for its services, United gained the benefit of such services at no cost to United and/or its plans.

162. United's wrongful conduct, as described above, unjustly enriched United to the detriment of Plaintiff.

**COUNT V**  
**Negligent Misrepresentation**  
(Against Defendant UnitedHealth Group Inc.)

163. Genomind realleges and incorporates by reference as if set forth fully herein the allegations contained in paragraphs 1 through 131.

164. As set forth herein, without limitation, United and/or its agent Beacon consistently represented that: the United Insureds had health benefits coverage with or through United for the services at issue; and United would pay Genomind for such services. In connection with these claims, United and/or Beacon also specifically provided prior authorization for the services

provided by Genomind where applicable, thereby verifying that Genomind would be permitted to bill United for such services and would be paid for providing such services to the United Insureds. United and/or Beacon, as United's agent, further repeatedly assured Genomind that its Core 15 Test fell within United's internal coverage policy.

165. Genomind reasonably believed such representations to be accurate at the time they were made and received. If, however, such representations were not accurate, then such representations constituted untrue statements of fact.

166. Contrary to the representations repeatedly made by United and/or Beacon to Genomind, United did not intend to and did not pay Genomind for the services it provided to the United Insureds. As such, United, in the course of its business, made false representations to Genomind for guidance in Genomind's business.

167. At the time of the representations, United owed Genomind a duty as a business partner to take reasonable care in making representations about payment.

168. United either acted negligently or failed to exercise reasonable care in making the aforementioned representations to Genomind because United ought to have known of their falsity.

169. Whether United would pay Genomind for performing such services is a material fact with respect to how Genomind and United conduct their businesses.

170. Genomind reasonably relied, to its detriment, on the misrepresentations United and/or Beacon made in this regard. Among other things, Genomind would not have invested substantial time and resources to develop a 15-gene test, or provided the services it did for the benefit of the United Insureds, had United and/or Beacon advised Genomind that Genomind could not bill United for the services, that Genomind had been placed into pre-payment review by United, and/or that United would not pay Genomind for providing medically necessary services to the United Insureds.



171. Said negligent misrepresentations by United and/or Beacon proximately caused damages to Genomind.

**COUNT VI**  
**Violation of ERISA under 29 U.S.C. § 1132(a)(1)(B)**  
(Against all Defendants)

172. Genomind realleges and incorporates by reference as if set forth fully herein the allegations contained in paragraphs 1 through 131.

173. This Count is a claim under ERISA, 29 U.S.C. § 1132(a)(1)(B), to recover benefits due to Genomind or the United ERISA Insureds 1-3391 (to be identified later, subject to an appropriate confidentiality agreement), to enforce their rights under the terms of the United plans, or to clarify their rights to future benefits under the terms of the plans.

174. The ERISA Claims arise under employee health benefit plans in favor of the United Insureds who receive their health insurance from United plans that are governed by ERISA and who have authorized Genomind to bring this action on their behalf.

175. These United Insureds sought treatment for medical services that are covered under such ERISA plans, and United is a payor under such plans or otherwise has been delegated the responsibility to make benefit determinations under such plans and to pay benefits that are due and owing under the plan terms and conditions. As such, United is an ERISA fiduciary with respect to the ERISA claims at issue in this action.

176. As a result of the medical treatment provided by Genomind, the United ERISA Insureds incurred necessary medical charges that are covered by their ERISA plans.

177. Pursuant to the assignments provided by the United ERISA Insureds, Genomind has been granted the legal right to assert these ERISA claims and is thereby entitled to enforce the terms of the applicable United plans.

178. United breached the terms of the ERISA plans and violated ERISA by failing to pay Genomind for out-of-network benefits covered by such plans. Pursuant to 29 U.S.C. § 1132(a)(1)(B) and the authorizations, Genomind is entitled to enforce such plan terms and recover the plan benefits due.

179. Genomind has performed, or is excused from performing, any and all obligations required of it under United's respective health benefit plans or otherwise.

180. Among other things, Genomind has exhausted, or is excused from exhausting, any and all administrative remedies. Furthermore, in light of the foregoing and otherwise, additional administrative efforts to obtain payment from United would be futile or there has been deemed exhaustion under ERISA and its accompanying regulations issued by the Department of Labor.

181. Due to the ERISA violations detailed herein, Genomind is entitled to appropriate relief under ERISA, 29 U.S.C. §1132(a)(1)(B).

WHEREFORE, Genomind respectfully requests that this Court enter judgment in its favor and against United, as follows:

- a. Awarding compensatory damages in favor of Genomind and against United in an amount to be determined at trial;
- b. Awarding punitive damages in favor of Genomind and against United in an amount to be determined at trial;
- c. Awarding Genomind benefits pursuant to the written United plan terms in an amount to be determined at trial, while enforcing the United ERISA Insureds' right under their United plans and clarifying their rights to future benefits under such plans, pursuant to ERISA, 29 U.S.C. § 1132(a)(1)(B);
- d. Granting Genomind its attorney's fees and expenses, including court costs incurred in connection with this action;

- e. Granting Genomind interest, as appropriate, from 30 days after each applicable bill was submitted to United; and,
- f. Granting such other relief as the Court deems appropriate, equitable, and just.

**JURY DEMAND**

Genomind demands a trial by jury for Counts I through V.

Date: January 27, 2021

*s/ Jason B. Martin*

Jason B. Martin

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